IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	10/517,686
Applicant	:	Evert Johannes Bunschoten et al.
Filed	:	June 30, 2005
Title	:	Method of Treating or Preventing Immune Mediated Disorders and Pharmaceutical Formulation for Use Therein
Art Unit	:	1609
Examiner	:	Mei Ping Chui
Confirmation No.	:	3094
Customer No.	:	28289

MAIL STOP AMENDMENT
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

ELECTION WITH TRAVERSE

Sir:

This is in response to the Office Action, dated April 3, 2007, issued by the Examiner in connection with the above-referenced application. A one-month Petition for an Extension of Time, extending the deadline for response until June 3, 2007, which falls on a Sunday, extending the due date until Monday, June 4, 2007, is submitted herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on June 4, 2007.

Jennifer L. Halkias
(Name of Person Mailing Paper)

Jennifer Halkias June 4, 2007
Signature Date

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In view of the following remarks, reconsideration of the restriction requirement is respectfully requested.

Claims 18-33 are pending in this application. In the Office Action, the Examiner requires restriction under 35 U.S.C. §121 and §372 between the following allegedly distinct groups I-XVI. Upon the election of one of the inventions, the Examiner is further requiring a species election with respect to methods of administering and/or pharmaceutical formulations comprising an estrogenic component and a specific immunotherapeutic agent.

The Examiner has stated that claims 18 and 22-28 are generic to each of the species of any of the Groups I-XV inventions. The Examiner has also stated that claims 19-31 and 33 are generic to each of the species of the Group XVI invention.

Applicants hereby elect the invention of Group I, drawn to a method of treating or preventing an immune mediated disorder in a mammal wherein the immune mediated disorder comprises autoimmune diseases, with traverse. In view of the requirement for a further species election, the species 1,3,5(10)-estratien-3,15,16,17-tetrol is further elected with traverse. Claims 18 and 22-28 are deemed generic by the Examiner. These claims are also readable on the elected species.

Applicants respectfully traverse the restriction requirement for the following reasons. The Examiner states that the inventions listed as Groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature. The Examiner also states that the technical feature linking Groups I-XVI is the estrogenic compound,

estetrol, which is however, taught by Dullien et al and would therefore not constitute a special technical feature defining the contribution over the prior art.

Applicants respectfully disagree with the Examiner's position. The special technical feature linking the Group I-XV inventions is the use of a specific class of estrogenic compounds for treating an immune-mediated disorder in a mammal. This is immediately apparent from the language of claim 18 and is not altered by the fact that claim 18 contains certain further limitations with regard to the specific selection of immune mediated disorders.

Accordingly, the invention resides in the finding that the estrogenic compounds of the invention affect the immune system in such a way that they can advantageously be applied in methods of treating disorders wherein the immune system is implicated. The list of disorders in claim 18 is thus not a random selection of disorders.

The Examiner has failed to cite any prior art disclosure or teaching anticipating and/or obviating the special technical feature of the use of any estrogenic compound from the class to which claim 18 is limited for treating and/or preventing any immune mediated disorder.

It is Applicants' position that a claim corresponding to claim 18, without the limitation as to the specific types of immune mediated disorders, would not have become the subject of any restriction requirement, in view of the prior art. The inclusion of a list of specific immune mediated disorders, which were introduced during the PCT phase, for reasons not pertaining to the prior art, does not justify a restriction requirement. The Examiner will note that this same main claim, written according to

European practice, was present during the PCT International Preliminary Examination stage and no such objection was made.

The restriction between the Group XV invention, drawn to a method of treating or preventing an immune mediated disorder in a mammal, and the Group XVI invention, drawn to a pharmaceutical formulation comprising an estrogenic component and an oral unit dosage form of the formulation, is also improper. Applicants respectfully traverse this restriction as the specific class of estrogenic compounds of the invention can advantageously be applied for treating immune mediated disorders. Thus, the corresponding technical feature can be defined as the specific estrogenic compounds in combination with an immunotherapeutic agent. Therefore, the claims of the Group XV invention are directed to a product specifically adapted for the method of treatment of claim 18, the restriction thereof being improper as per 37 CFR § 1.475(b)(4).

Applicants also note that restriction between the Group I-XVI inventions and the allegedly distinct species is improper as the search directed to any of these inventions defined by Groups I-XVI and/or species would clearly overlap. Such coextensive searching would not present any undue burden on the Examiner for examination of all of the claims.

In view of the above remarks, withdrawal of the restriction requirement is respectfully solicited.

Respectfully Submitted,

The Webb Law Firm

By _____

William H. Logsdon
Registration No. 22,132
Attorney for Applicants
700 Koppers Building
436 Seventh Avenue
Pittsburgh, PA 15219
Telephone: 412-471-8815
Facsimile: 412-471-4094
E-mail: webblaw@webblaw.com